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10/772,944	02/05/2004	John E. Kast	151P08970US02	5311

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EXAMINER	
BUSTAMANTE, ERIK J	
ART UNIT	**PAPER NUMBER**
3766	

DATE MAILED: 09/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/772,944	KAST ET AL.	
	Examiner	Art Unit	
	Erik J. Bustamante	3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 February 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *05 February 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *8/27/04 5/18/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Priority

1. Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has complied with the conditions for receiving the benefit of an earlier filing date under 35 U.S.C.

Information Disclosure Statement

2. The information disclosure statement filed 8/17/2004 fails to comply with 37 CFR 1.98(a)(3) because it does not include a concise explanation of the relevance, as it is presently understood by the individual designated in 37 CFR 1.56(c) most knowledgeable about the content of the information, of each patent listed that is not in the English language. It has been placed in the application file, but the information referred to therein has not been considered. The aforementioned IDS cite two German patents but the applicant has failed to provide a translated copy or statement of relevance.

3. The information disclosure statement (IDS) submitted on 5/18/2004 is in compliance of 37 CFR 1.97. All the references cited are in compliance with the provisions of 37 CFR 1.98. Accordingly, the information disclosure statement is being considered by the examiner.

Drawings

4. Acknowledgement is made of applicant's drawings, which was received by the Office on February 5,2004.

Specification

5. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

The following title is suggested: "Implantable Medical Device with External Housing for a Recharging Coil."

6. The disclosure is objected to because of the following informalities:

a. The specification contains a reference or references to commonly owned patent applications without application numbers. The examiner respectfully requests that this information be updated along with any other referenced applications without application numbers or referenced applications that have since issued.

b. The specification contains references to parent applications by their application numbers. Some or all of these applications have since been issued or abandoned. The examiner respectfully requests that the parent application information be updated in the specification along with any other referenced application numbers in the specification that have matured into patents.

Appropriate correction is required.

7. The abstract of the disclosure is objected to because the phrase "is disclosed" is considered language, which can be implied. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

Correction is required. See MPEP § 608.01(b).

Claim Objections

8. The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

Misnumbered claims 5-23 has been renumbered 4-22.

9. Claim 13 is objected to because of the following informalities: the phrase "accomplished in an in situ mold" should be rewritten as "accomplished in situ" to be in accordance with standard scientific practice, and to further avoid any possible confusion. Appropriate correction is required.

10. Claim 22 is objected to because of the following informalities: the limitation "the means for recharging coil" lacks sufficient antecedent basis. The applicant does not recite within the claim "a means for recharging coil." Furthermore, it is unclear whether the applicant is referring to "the mean for recharging" cited earlier in the claim. Appropriate correction is required.

Double Patenting

11. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims

are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Omum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

12. Claims 1,2,7,8,18-19, and 20-22 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1,12-15,and 19-20 of U.S. Patent No. 6,505,077 B1.

For double patenting to exist as between the rejected claims and the patent claims, it must be determined that the rejected claims are not patentably distinct from claims 1,12,and 19-20. In order to make this determination, it first must be determined whether there are any differences between the rejected claims and claims 1,12-15,and 19-20 and, if so, whether those differences render the claims patentably distinct.

The difference between claims 1,2,7,8,18-19, and 20-22 of the application and claims 1,12-15,and 19-20 of the patent lies in the fact that the patent claim includes many more elements and is thus much more specific. It is clear that all the elements of claims 1,2,7,8,18-19, and 20-22 are to be found in claims 1,12-15,and 19-20. Thus, the invention of claims 1,12-15,and 19-20 of the patent is in effect a "species" of the

"generic" invention of claims 1,2,7,8,18-19, and 20-22 of the application. It has been held that the generic invention is "anticipated" by the "species". See In re Goodman, 29 USPQ2d 2010 (Fed. Cir. 1993). Since claims 1,2,7,8,18-19, and 20-22 are anticipated by claims 1,12-15,and 19-20 of the patent, they are not patentably distinct from claims 1,12-15,and 19-20.

35 USC § 112 6th paragraph

13. Regarding claim 21, the examiner has noticed that the applicant is attempting to invoke 112 6th paragraph protections for the "means of recharging/means for recharging coil." While this limitation passes the first prong of the 3 prong test to qualify for 112 6th paragraph protection, the limitations of "means of recharging/means for recharging coil" fails the third prong of the 3 prong test. Therefore, the examiner makes official record that the applicant has **not** complied with the regulations under 112 6th paragraph. Regarding "means of recharging/means for recharging coil", this limitation fails the third prong because the applicant recites significant structure used to accomplish the function of recharging the medical device in the preamble of the claim and in the recitation of "means of recharging coil" the use of the word "coil" disqualifies the limitation from obtaining 112 6th paragraph protection.

Claim Rejections - 35 USC § 112

14. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

15. Claim 21 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The applicant is invoking 112 6th; the applicant has failed to specifically define what "the means of attachment" are. Applicant refers to both encapsulation/overmolding and housing attachment details as ways in which the recharging coil is attached to the housing. Therefore, it is unclear to which of the aforementioned attachment mechanisms is the applicant attempting to seek 112 6th paragraph protection for. Furthermore, while the applicant has given an explicit definition for housing **alignment** details, the applicant has given no such definition for housing **attachment** details. If the applicant wishes to seek 112 6th paragraph protection for the housing **attachment** details then an explicit definition of what said details encompass is required. Refer to MPEP § 2181 for further details.

Claim Rejections - 35 USC § 102

16. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

17. Claims 1-3,5-7,11-13,17,19-21 are rejected under 35 U.S.C. 102(e) as being antcipated by LEYSIEFFER (6,154,677).

Regarding claim 1, LEYSIEFFER discloses an implantable medical device with an external recharging coil (106), comprising: a housing (104) having an interior cavity (Fig 1), a proximal face, and an electrical feedthrough (108); electronics (54) carried in the housing interior cavity (Fig 1); a rechargeable power source (90) carried in the housing interior cavity (Fig 1) and electrically coupled to the electronics (74,76); and, a recharging coil (54).

Regarding claim 2, LEYSIEFFER discloses a recharge feedthrough (108) located on the housing proximal surface (Fig 1).

Regarding claims 3 and 11-13, LEYSIEFFER discloses the mechanical attachment of the coil via the use of polymer which the examiner interprets to read upon polymer encapsulation and overmolding in situ (Col 2 lines 50-52, Col 4 lines 50-54).

Regarding claim 5, LEYSIEFFER discloses a coil cover (104) attached to the housing (Fig 1).

Regarding claims 6 and 7, LEYSIEFFER discloses a cover alignment/attachment detail (Col 4 lines 14-19).

Regarding claim 17, LEYSIEFFER discloses a battery (90) which by definition would qualify as a chemical storage device.

Regarding claim 19, LEYSIEFFER discloses a recharging coil multiplexing as a telemetry coil (Col 6 lines 51-58).

Regarding claim 20, LEYSIEFFER discloses that said device is from the group comprising hearing implant, cardiac pacemaker, defibrillator, drug dispenser, and neurostimulator (Col 2 lines 9-11).

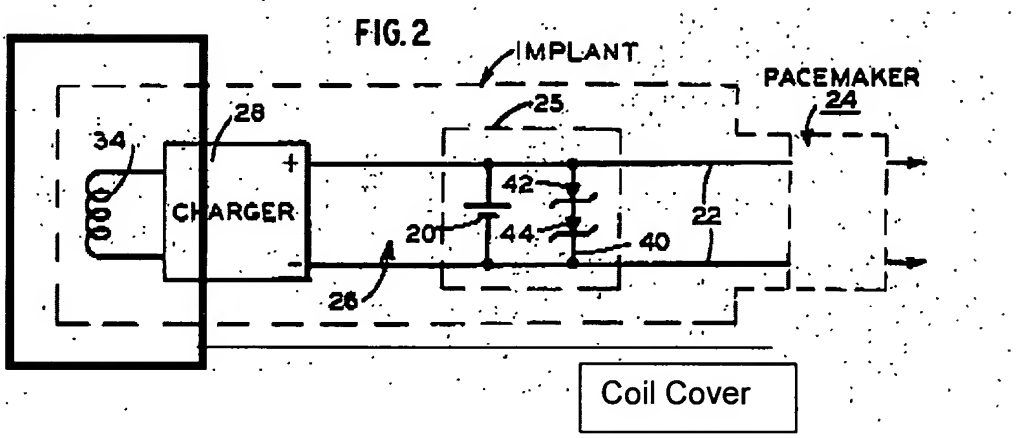
Regarding claim 21, LEYSIEFFER discloses a device comprising a housing (104) having an electrical feedthrough (108); electronics (54) carried in the housing interior; a rechargeable power source (90) and electrically coupled to the electronics (Fig 1); and, means for recharging (106) carried on the housing proximal face (Fig 1) and operationally coupled to recharge the rechargeable power source (90); and means for attaching (Col 4 lines 14-19) the means for recharging coil to a position centrally located and substantially carried on the housing proximal face (Fig 5).

18. Claims 1,5,and 9 are rejected under 35 U.S.C. 102(b) as being anticipated by FAGAN Jr. (3,824,129).

Regarding claim 1, FAGAN Jr. discloses an implantable medical device with an external recharging coil (34), comprising: a housing having an interior cavity (Fig 2), a proximal face, and an electrical feedthrough (22); electronics (24) carried in the housing interior cavity (Fig 2); a rechargeable power source (20) carried in the housing interior cavity (Fig 2) and electrically coupled to the electronics (22); and, a recharging coil (34).

Regarding claim 5, FAGAN Jr. discloses a coil cover (see Figure below), which inherently is attached to the housing. The examiner interprets the area covering

the coil (34) to function as the coil cover and the area covering the rest of the electronics to be the housing.



Regarding claim 9, FAGAN Jr. discloses a coil alignment carrier (28), which carries the coil, the coil alignment carrier positioned between the coil cover and the housing (see the Figure above).

19. Claims 1,5,8,11,17 and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by FISCHELL (3,888,260) as disclosed by the applicant.

Regarding claim 1, FISCHELL discloses an implantable medical device with an external recharging coil (20), comprising: a housing (13) which inherently has an interior cavity, a proximal face, and an electrical feedthrough (30); electronics (10-11) carried in the housing interior cavity (Fig 1a,b); a rechargeable power source (19) carried in the housing interior cavity (Fig 1b) and electrically coupled to the electronics (30); and, a recharging coil (20).

Regarding claim 5, FISCHELL discloses a coil cover (18), attached to the housing (Col 4 lines 36-53).

Regarding claim 8, FISCHELL discloses a biocompatible polymer to create a hermetic seal between the coil cover and the housing (Col 4 lines 36-53).

Regarding claim 11, FISCHELL discloses that the recharging coil is attached to the housing by encapsulation with a polymer (Col 5 lines 16-22).

Regarding claim 17,FISCHELL discloses that the rechargeable power source is a battery, which by definition would qualify as a chemical storage device (Col 6 line 43).

Regarding claim 19, FISCHELL discloses a recharging coil (39 & 20) configured to multiplex as a telemetry coil (Col 7 lines 15-22).

20. Claims 1, 16, and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by BAUMANN et al (5,279,292).

Regarding claim 1, BAUMANN discloses an implantable medical device with an external recharging coil (15), comprising: a housing (10) with an electrical feedthrough (19,20); electronics (12) carried in the housing interior cavity (Fig 1); a rechargeable power source (16) carried in the housing interior cavity (Fig 1) and electrically coupled to the electronics (19,20); and, a recharging coil (15).

Regarding claim 16, BAUMANN discloses the use of a capacitor (16) as the rechargeable power source which by definition would qualify as an electrical power source.

Regarding claim 18, BAUMANN discloses the use of a telemetry circuit (45) which would inherently include a telemetry coil located in the housing interior cavity (Fig 1).

21. Claims 1-7,9,14,16, and 20-22 are rejected under 35 U.S.C. 102(b) as being anticipated by SUSSET et al (3,667,477).

Regarding claim 1, SUSSET discloses an implantable medical device with an external recharging coil (102), comprising: a housing (101) with an electrical feedthrough (103,104); electronics (12); a rechargeable power source (106) carried in the housing interior cavity (Fig 3) and electrically coupled to the electronics (109); and, a recharging coil (102).

Regarding claim 2, SUSSET discloses a recharge feedthrough (103,104) located on the housing proximal surface (Fig 3).

Regarding claim 3, SUSSET discloses that the recharging coil is mechanically attached to the housing (Fig 3).

Regarding claims 4,6,and 7, SUSSET discloses a cover/housing attachment detail used to attach a coil cover to a housing (16). The aforementioned attachment detail can also inherently be used as an alignment detail.

Regarding claim 5 and 14, SUSSET discloses a coil cover/retention sleeve (11) that attaches to the housing (Fig 1) and carries the recharging coil (Fig 3).

Regarding claim 9, SUSSET discloses a coil alignment carrier
for carrying the coil (Col 2 lines 36-39), the coil alignment carrier positioned between the coil cover and the housing (Fig 3). SUSSET discloses the use of a ferrite rod to hold and carry the coil (102); therefore the examiner considers the ferrite, which is not depicted in the drawings to be the coil carrier.

Regarding claim 16, SUSSET discloses the use of a capacitor (106), which by definition would be classified as an electrical power storage source.

Regarding claim 20, SUSSET discloses a device capable of stimulating the smooth muscle of the bladder (see abstract). The examiner takes the position that one of ordinary skill in the art would easily recognize that said device could be used as a neuro stimulator.

Regarding claim 21, SUSSET discloses a device comprising a housing (101) having an electrical feedthrough (103,104); electronics (12) carried in the housing interior; a rechargeable power source (106) and electrically coupled to the electronics (Fig 3); and, means for recharging (102) carried on the housing proximal face (Fig 3) and operationally coupled to recharge the rechargeable power source (106); and means for attaching (16) the means for recharging coil to a position centrally located and substantially carried on the housing proximal face.

Regarding claim 22, SUSSET discloses an implantable medical device with an external recharging coil (102), comprising: a housing having an electrical feedthrough (103,104), the housing having at least one housing alignment detail (16); electronics (12) carried in the housing interior cavity,

a rechargeable power source (106) coupled to the electronics (Fig 3);

a recharging coil (102) carried on the housing proximal face and electrically coupled through the housing electrical feedthrough to the electronics and rechargeable power source (Fig 3).

Claim Rejections - 35 USC § 103

22. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

23. Claims 10 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over SUSSET as applied to claims 9 and 14 above, and further in view of FISCHELL.

Regarding claims 10 and 15, SUSSET discloses the claimed invention except for the hermetic sealing of the retention sleeve and coil alignment carrier to the housing. FISCHELL teaches the use of hermetic sealing in the manufacture of a pacemaker. FISCHELL states that hermetic sealing "protects the electronic components from exposure to corrosive fluids from the body (abstract)." Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have hermetically sealed the retention sleeve and coil alignment carrier to the housing in the device of SUSSET, in light of the teachings of FISCHELL, to provide protection for the electronic components found in the device of SUSSET.

24. Claims 12 and 13 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over FAGAN Jr. as applied to claim 1. FAGAN Jr. is as explained before. FAGAN Jr. shows the recharging coil (34) connected to the connector module (Fig. 2). Although FAGAN Jr. fails to show the recharging coil is attached via overmolding in an in situ mold, the examiner has

interpreted this limitation to render claims 12 and 13 product-by-process claims since overmolding is a process for connecting parts. The claimed product appears to be the same or similar to the prior art because the only difference is in the way in which the retention element and the surrounding connector module have been physically united.

As set forth in MPEP 2113, product by process claims are NOT limited to the manipulations of the recited steps, only to the structure implied by the steps. Once a product appearing to be substantially the same or similar is found, a 35 U.S.C. 102/103 rejection may be made and the burden is shifted to applicant to show an unobvious difference. See MPEP 2113.

25. Claims 12 and 13 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over LEYSIEFFER as applied to claim 1. LEYSIEFFER is as explained before. LEYSIEFFER shows the recharging coil (34) connected to the connector module (Fig. 2). Although LEYSIEFFER fails to show the recharging coil is attached via overmolding in an in situ mold, the examiner has interpreted this limitation to render claims 12 and 13 product-by-process claims since overmolding is a process for connecting parts. The claimed product appears to be the same or similar to the prior art because the only difference is in the way in which the retention element and the surrounding connector module have been physically united.

As set forth in MPEP 2113, product by process claims are NOT limited to the manipulations of the recited steps, only to the structure implied by the steps. Once a product appearing to be substantially the same or similar is found, a 35 U.S.C. 102/103

rejection may be made and the burden is shifted to applicant to show an unobvious difference. See MPEP 2113.

Conclusion

26. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

2002/0084881 A1 KUMMEL, discloses overmolding an inductive component on to a circuit board as a method for providing a tighter seal to protect the inductor in a wet environment.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Erik J. Bustamante whose telephone number is 571-272-8820. The examiner can normally be reached on Mon-Fri (7:30 - 11:30 AM).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Pezzuto can be reached on 571-272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Erik J Bustamante
Examiner
Art Unit 3766

Robert E. Pezzuto
Supervisory Patent Examiner
Art Unit 3766

EJB